

NOTICE OF PROPOSED REGULATION ADOPTION

**California Code of Regulations
Title 17. – Public Health
Division 4 - California Institute For Regenerative Medicine
Chapter 5**

Date: February 8, 2008

Deadline for Submission of Written Comment: March 24, 2008 – 5:00 p.m.

Hearing Date: None scheduled.

Subject Matter of Proposed Regulations: Grant Administration Policy for For-Profit Organizations

Sections Affected:

The proposed regulation adopts Chapter 5, section 100501, of Title 17 of the California Code of Regulations.

Authority: Article XXXV of the California Constitution and Health and Safety Code section 125290.40, subdivision (j).

Reference: Sections 125290.30, 125290.40, 125290.60, 125290.70, 125292.10, Health and Safety Code.

Informative Digest/Policy Statement Overview:

The California Institute for Regenerative Medicine (“Institute” or “CIRM”) was established in early 2005 with the passage of Proposition 71 (the “Act”), the California Stem Cell Research and Cures Initiative. The statewide ballot measure, which provides \$3 billion in funding for stem cell research and dedicated facilities at California universities and research institutions, was approved by California voters on November 2, 2004, called for the establishment of a new state agency to make grants and provide loans for stem cell research, research facilities and other vital research opportunities.

The Independent Citizens’ Oversight Committee (“ICOC”) is the 29-member governing board for the Institute. The ICOC members are public officials, appointed on the basis of their experience earned in California's leading public universities, non-profit academic and research institutions, patient advocacy groups and the biotechnology industry.

The Act charges the ICOC with developing standards and criteria to make grant awards and to develop standards and criteria for proper oversight of awards. (§ 125290.50.) To that end, the CIRM developed a document titled “Interim CIRM Grants Administration Policy for For-Profit Organizations.” This policy serves to guide for-profit grant

recipients on their responsibilities as CIRM grantees. Principal investigators, program directors, and organizational officials with grants management responsibilities may refer to pertinent sections for answers to questions that arise concerning the administration of the grants. By accepting a CIRM grant award, the for-profit grantee is agreeing to comply with the provisions set forth in the policy for the entire project period of the grant, in addition to provisions of the CIRM grants administration policy already adopted by the ICOC and codified in Title 2, California Code of Regulations section 100500.

The policy incorporated by the regulation sets forth the rules governing the eligibility of Principal Investigators and Program Directors for, describes requirements for sharing of publication-related biomedical materials, standards for allowable costs and activities chargeable to the grant, changes that require prior approval from the CIRM, reporting requirements, close-out rules and written notification requirements.

Technical, Theoretical or Empirical Studies, Reports or Documents:

A. Documents or Laws:

- Title 2, California Code of Regulations, section 100500 – Grants Administration Policy for Non-Profit and Academic Institutions (http://www.cirm.ca.gov/reg/pdf/reg100500_policy.pdf)

B. Public Input:

Discussion and public input received at two public meetings conducted by the CIRM on September 7, 2007, and November 16, 2007.

Copies of the documents referenced above are available at the internet link indicated or at the offices of CIRM located at 210 King Street, San Francisco, California, 94107.

Submittal of Comments:

Any interested party may present comments in writing about the proposed action to the agency contact person named in this notice. Written comments must be received no later than 5:00 p.m. on March 24, 2008. Comments regarding this proposed action may also be transmitted via e-mail to forprofitgap@cirm.ca.gov or by facsimile transmission to (415) 396-9141.

At this time, no public hearing has been scheduled concerning the proposed regulations. If any interested person or the person's representative requests a public hearing, he or she must do so in writing no later than March 10, 2008.

Effect on Small Business:

CIRM has determined that the proposed regulatory action has no impact on small businesses. The regulation implements conditions on awarding grants for stem cell research. This research is conducted almost exclusively by large public and private non-profit institutions, as well as large for-profit institutions. As such, the regulation is not expected to adversely impact small business as defined in Government Code section 11342.610.

Impact on Local Agencies or School Districts:

CIRM has determined that the proposed regulatory action does not impose a mandate on local agencies or school districts, nor does it require reimbursement by the state pursuant to Part 7 (commencing with section 17500) of Division 4 of the Government Code because the regulatory action does not constitute a “new program or higher level of service of an existing program” within the meaning of section 6 of Article XIII of the California Constitution. CIRM has also determined that no nondiscretionary costs or savings to local agencies or school districts will result from the proposed regulatory action.

Costs or Savings to State Agencies:

CIRM has determined that no savings or increased costs to any agency will result from the proposed regulatory action.

Effect on Federal Funding to the State:

CIRM has determined that no costs or savings in federal funding to the state will result from the proposed regulatory action.

Effect on Housing Costs:

CIRM has made an initial determination that the proposed action will have no effect on housing costs.

Significant Statewide Adverse Economic Impact Directly Affecting Businesses:

CIRM has made an initial determination that adoption of this regulation will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California Businesses to compete with businesses in other states.

Cost Impacts on Representative Private Persons or Businesses:

CIRM has made an initial determination that the adoption of this regulation will not have a significant cost impact on representative private persons or businesses. The CIRM is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action.

Impact on the Creation, Elimination, or Expansion of Jobs:

CIRM has determined it is unlikely the proposed regulatory action will impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California.

Consideration of Alternatives:

CIRM must determine that no reasonable alternatives considered by the agency, or that have otherwise been identified and brought to the attention of the agency, would be more effective in carrying out the purpose for which the action is proposed or would be as effective and less burdensome to affected private persons or businesses than the regulatory action.

Availability of Statement of Reasons and Text of Proposed Regulations:

CIRM has prepared an Initial Statement of Reasons, and has available the express terms of the proposed action, all of the information upon which the proposal is based, and a rulemaking file. A copy of the Initial Statement of Reasons and the proposed text of the regulation may be obtained from the agency contact person named in this notice. The information upon which CIRM relied in preparing this proposal and the rulemaking file are available for review at the address specified below.

Availability of Changed or Modified Text:

After the close of the comment period, CIRM may make the regulation permanent if it remains substantially the same as described in the Policy Statement Overview. If CIRM does make changes to the regulation, the modified text will be made available for at least 15 days prior to adoption. Requests for the modified text should be addressed to the agency contact person named in this notice. CIRM will accept written comments on any changes for 15 days after the modified text is made available.

Agency Contact:

Written comments about the proposed regulatory action; requests for a copy of the Initial Statements of Reasons, the proposed text of the regulation, and a public hearing; and inquiries regarding the rulemaking file may be directed to:

Tamar Pachter, General Counsel
California Institute for Regenerative Medicine
210 King Street
San Francisco, CA 94107
(415) 396-9100

Questions on the substance of the proposed regulatory action may be directed to:

Patricia Olson, Interim Director of Scientific Activities
California Institute for Regenerative Medicine
(415) 396-9116

The Notice of Proposed Regulatory Adoption, the Initial Statement of Reasons and any attachments, and the proposed text of the regulations are also available on CIRM's website, www.cirm.ca.gov.

Availability of Final Statement of Reasons:

Following its preparation, a copy of the Final Statement of Reasons mandated by Government Code section 11346.9, subdivision (a), may be obtained from the contact person named above. In addition, the Final Statement of Reasons will be posted on CIRM's webpage and accessed at www.cirm.ca.gov.